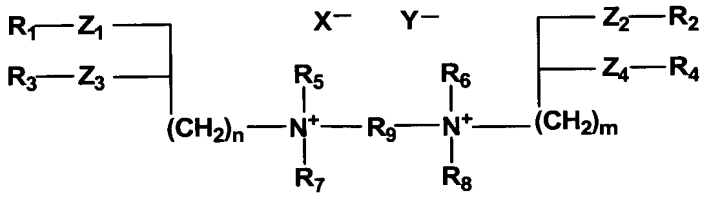
Amendments to the Claims

This listing of claims will replace all prior versions, and listings of, claims in the application.

Claims 1-46 (cancelled).

47. (previously presented) A cationic lipid compound of the following formula



wherein

Z_1, Z_2, Z_3 and Z_4 are the same or different and are -O-C(O)- or -O-;

R_1 and R_2 are the same or different and are H, C_1 to C_{24} alkyl or C_1 to C_{24} alkenyl;

R_3 and R_4 are the same or different and are C_1 to C_{24} alkyl or C_1 to C_{24} alkenyl;

R_5, R_6, R_7 and R_8 are the same or different and are H, C_1 to C_{10} alkyl or C_1 to C_{10} alkenyl;

R_9 is a linker;

n and m are the same or different and are 1 to 8; and

X and Y are the same or different and are non-toxic anions;

provided that when R_9 is a straight-chain alkylene having 3-6, 12, 16, 20, or 22 carbons, then all of R_1, R_2, R_3, and R_4 are not H, all of R_5, R_6, R_7, and R_8 are not methyl, m and n are not 1, and all of Z_1, Z_2, Z_3, and Z_4 are not O.

48. (previously presented) The compound of claim 47, wherein R_9 comprises

C_1 to C_{10} substituted alkyl;

C_1 to C_{10} alkyloxy;

C_1 to C_{10} substituted alkyloxy;

C_1 to C_{10} alkenyl;

C_1 to C_{10} substituted alkenyl;

C_1 to C_{10} alkenyloxy;

C_1 to C_{10} substituted alkenyloxy;

$-NR_{10}-C(O)-NR_{11}-$, wherein R_{10} and R_{11} are independently H, C_1 to C_{10} alkyl, C_1 to C_{10} substituted alkyl, C_1 to C_{10} alkenyl, or C_1 to C_{10} substituted alkenyl;

$-NR_{12}-C(O)-NR_{13}-R_{16}-NR_{14}-C(O)-NR_{15}-$, wherein R_{12}-R_{15} are independently H, C_1 to C_{10} alkyl, substituted C_1 to C_{10} alkyl, C_1 to C_{10} alkenyl, or C_1 to C_{10} substituted alkenyl, and R_{16} is independently C_1 to C_{10} alkyl or C_1 to C_{10} substituted alkyl;

$-C(O)-NR_{17}-$, wherein R_{17} is H, C_1 to C_{10} alkyl, C_1 to C_{10} substituted alkyl, C_1 to C_{10} alkenyl, and C_1 to C_{10} substituted alkenyl;

polyalkyloxy group; amino acid; peptide; saccharide; polypeptide; polysaccharide; protein; polyamine; peptidomimetic moiety; histone; moiety with DNA binding affinity; or moiety with cell receptor binding affinity.

49. (previously presented) The compound of claim 48, wherein R_9 comprises C_1 to C_{10} substituted alkyl, C_1 to C_{10} alkenyl or C_1 to C_{10} substituted alkenyl.

50. (previously presented) The compound of claim 49, wherein R_9 further comprises a peptide linkage.

51. (previously presented) The compound of claim 50, wherein the cationic lipid compound is HB-DMRIE-Ox-Trp-γ-DMRIE.

52. (previously presented) The compound according to claim 47, wherein R_9 comprises an optionally substituted polyalkyloxy group.

53. (previously presented) The compound according to claim 52, wherein the polalkyloxy group contains from 1 to about 500 alkyloxy mers.

54. (previously presented) The compound according to claim 53, wherein the polyalkyloxy group contains from 1 to about 100 alkyloxy mers.

55. (previously presented) The compound according to claim 54, wherein the cationic lipid compound is PentaEG-bis-DMRIE.

56. (previously presented) The compound according to claim 54, wherein R_9 further comprises a peptide linkage.

57. (previously presented) The compound according to claim 56, wherein the cationic lipid compound is PEG34-bis-But-DMRIE-propylamide.

58. (previously presented) The compound of claim 49, wherein the linker comprises a ureyl or bis-ureyl linkage.

59. (previously presented) The compound of claim 47, wherein R_9 is a moiety with DNA binding affinity or a moiety with cell receptor binding affinity.

60. (previously presented) The compound of claim 59, wherein R_9 is an amino acid, saccharide, peptide, polysaccharide, polypeptide, protein, polyamine, or peptidomimetic moiety.

61. (previously presented) The compound of claim 60, wherein R_9 is a protein.

62. (previously presented) The compound of claim 61, wherein said protein is selected from the group consisting of immunoglobulins, transferrins, asialoglycoproteins, integrins, cytokines, selectins, cell surface receptors, receptor ligands, major histocompatability proteins, lysosomotrophic proteins, histones, extracellular proteins, protein hormones, growth factors, bacterial exotoxins, low density lipoprotein, alpha-2-macroglobulin, and angiotensin.

63. (previously presented) The compound of claim 62, wherein said protein is a transferrin.

64. (previously presented) The compound of claim 62, wherein said protein is an immunoglobulin.

65. (previously presented) The compound of claim 62, wherein said protein is a histone.

66. (previously presented) The compound of claim 60, wherein R_9 is a polyamine.

67. (previously presented) The compound of claim 66, wherein said polyamine is spermine, spermidine, or a derivative thereof.

68. (currently amended) The compound of claim 47, wherein R_9 comprises $-R_{17}-NR_{12}-C(O)-NR_{13}-R_{16}-NR_{14}-C(O)-NR_{15}-R_{18}-$ wherein R_{12}-R_{15} are independently H, C_1 to C_{10} alkyl, substituted C_1 to C_{10} alkyl, C_1 to C_{10} alkenyl, or C_1 to C_{10} substituted alkenyl, R_{16} is independently C_1 to C_{10} alkyl or C_1 to C_{10} substituted alkyl, and R_{17} and R_{18} are independently optionally substituted C_1 to C_{10} alkyl or C_1 to C_{10} alkenyl.

69. (previously presented) The compound of claim 68, wherein the cationic lipid compound is SBDU-DMRIE, SBGU-DMRIE, or SHGU-DMRIE.

70. (previously presented) A composition comprising the compound of claim 47, and one or more co-lipids.

71. (previously presented) A composition comprising the compound of claim 51 and one or more co-lipids.

72.(previously presented) A composition comprising the compound of claim 55 and one or more co-lipids.

73. (previously presented) A composition comprising the compound of claim 57 and one or more co-lipids.

74. (previously presented) A composition of comprising the compound of claim 68 and one or more co-lipids.

75. (previously presented) A composition comprising the compound of claim 69 and one or more co-lipids.

76. (previously presented) An immunogenic composition comprising an immunogen and a compound of claim 47.

77. (previously presented) The immunogenic composition of claim 76, wherein said immunogen is an immunogen-encoding polynucleotide.

78. (previously presented) The immunogenic composition of claim 76 further comprising one or more co-lipids.

79. (previously presented) A method for inducing an immune response in a vertebrate, said method comprising administering to the vertebrate an immunogenic composition of claim 76 in an amount sufficient to generate an immune response to the encoded immunogen.

80. (previously presented) The method of claim 79, wherein the vertebrate is a mammal.

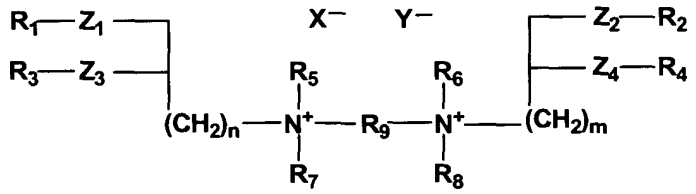
81. (previously presented) The method of claim 80, wherein the mammal is a human.

82. (previously presented) A method for delivering a biologically active agent to a cell of an animal, said method comprising:

contacting said cell with a lipid aggregate, said lipid aggregate comprising said biologically active agent and the compound of claim 47.

83. (previously presented) A pharmaceutical kit for use in delivering a polynucleotide to a vertebrate, said kit comprising:

a cationic compound of the formula



wherein

Z_1, Z_2, Z_3 and Z_4 are the same or different and are -O-C(O)- or -O-;

R_1 and R_2 are the same or different and are H, C_1 to C_{24} alkyl or C_1 to C_{24} alkenyl;

R_3 and R_4 are the same or different and are C_1 to C_{24} alkyl or C_1 to C_{24} alkenyl;

R_5, R_6, R_7 and R_8 are the same or different and are H, C_1 to C_{10} alkyl or C_1 to C_{10} alkenyl;

R_9 is a linker, wherein said linker comprises

C_1 to C_{10} substituted alkyl;

C_1 to C_{10} alkyloxy;

C_1 to C_{10} substituted alkyloxy;

C_1 to C_{10} alkenyl;

C_1 to C_{10} substituted alkenyl;

C_1 to C_{10} alkenyloxy;

C_1 to C_{10} substituted alkenyloxy;

$-NR_{10}-C(O)-NR_{11}-$, wherein R_{10} and R_{11} are independently H, C_1 to C_{10} alkyl, C_1 to C_{10} substituted alkyl, C_1 to C_{10} alkenyl, or C_1 to C_{10} substituted alkenyl;

$-NR_{12}-C(O)-NR_{13}-R_{16}-NR_{14}-C(O)-NR_{15}-$, wherein R_{12}-R_{16} are independently H, C_1 to C_{10} alkyl, substituted C_1 to C_{10} alkyl, C_1 to C_{10} alkenyl, or C_1 to C_{10} substituted alkenyl, and R_{17} is independently C_1 to C_{10} alkyl or C_1 to C_{10} substituted alkyl;

$-C(O)-NR_{17}-$, wherein R_{17} is H, C_1 to C_{10} alkyl, C_1 to C_{10} substituted alkyl, C_1 to C_{10} alkenyl, and C_1 to C_{10} substituted alkenyl;

polyalkyloxy group; amino acid; peptide; saccharide; polypeptide; polysaccharide; protein; polyamine; peptidomimetic moiety; histone; moiety with DNA binding affinity; or moiety with cell receptor binding affinity;

n and m are the same or different and are 1 to 8; and

X and Y are the same or different and are non-toxic anions.;

optionally co-lipid;

optionally a polynucleotide;

one or more containers, wherein said cationic compound, said optional co-lipid, and said optional polynucleotide are in the same or different said one or more containers; and

optionally means for administering to a vertebrate said cationic compound, said optional co-lipid, and said optional polynucleotide.

84. (previously presented) The pharmaceutical kit according to claim 83, wherein said kit further comprises a polynucleotide, wherein said polynucleotide operably encodes a polypeptide within vertebrate cells *in vivo*.

85. (previously presented) The pharmaceutical kit according to claim 84, wherein said kit contains 1 ng to 30 mg of said polynucleotide.

86. (previously presented) The pharmaceutical kit according to claim 85, wherein said kit contains about 100 ng to about 10 mg of said polynucleotide.

87. (previously presented) The pharmaceutical kit according to claim 83, wherein R_9 comprises an optionally substituted polyalkyloxy group.

88. (previously presented) The pharmaceutical kit according to claim 87, wherein said polyalkyloxy group contains from 1 to about 500 alkyloxy mers.

89. (previously presented) The pharmaceutical kit according to claim 88, wherein said cationic lipid compound is PentaEG-bis-DMRIE.

90. (previously presented) The pharmaceutical kit according to claim 88, wherein R_9 further comprises a peptide linkage.

91. (previously presented) The pharmaceutical kit according to claim 90, wherein said cationic lipid compound is PEG34-bis-But-DMRIE-propylamide.

92. (previously presented) The pharmaceutical kit according to claim 83, wherein said cationic lipid compound is HB-DMRIE-Ox-Trp-γ-DMRIE.

93. (previously presented) The pharmaceutical kit according to claim 83, wherein R_9 comprises a bis-ureyl linkage.

94. (previously presented) The pharmaceutical kit according to claim 93, wherein said cationic lipid compound is SBDU-DMRIE, SBGU-DMRIE or SHGU-DMRIE.

95. (previously presented) The compound according to claim 47, wherein X and Y are Br^-.

96. (previously presented) The compound according to claim 48, where X and Y are Br^-.

97. (previously presented) The compound according to claim 68, wherein X and Y are Br^-.